K073695 38

APR - 9 2008

510(k) SUMMARY
J. Morita USA Inc.'s 3D Accu-I-tomo XYZ Slice view Tomograph
Model : MCT-1EX-1F8/F17

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2353

2. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. Date summary prepared: January 24, 2008

4. Device Name:

Trade or Proprietary Name: 3D Accu-I-tomo XYZ Slice view tomograph
Model: MCT-1EX-1F8/F17

Note: The name is abbreviated to MCT-1EX-1F8/F17 in the 510(k) submission , and includes two kinds of actual models, MCT-1EX-1F8 and MCT-1EX-1F17 whose details are shown in Table-A below.

Common Name: Cone beam x-ray CT

Classification Name: Computed tomography x-ray system (21CFR892.1750)

Product Code : JAK

365

The MCT-1EX-1F8/F17 includes the actual model numbers specified with the main differences as shown in Table-A below.

Division	Actual model number	Main differences		
		Size of radiographic area size D x H (mm)	FPD used	Rotation arm
This submission	MCT-1EX-1F8	40x40 60x60 80x80	Made by Hamamatsu	Linear-shaped-C-arm
	MCT-1 EX-1F17	Note-1	Made by Varian	
The predicate	MCT-1EXF	40x40 60x60	Made by Hamamatsu	Round-shaped C-arm

Note-1: Selectable between 170 x 120mm and 40 x 40mm. (Diameter x Height)

Table-A Actual model numbers in MCT-1EX-1F8/F17

5. Substantial Equivalency is claimed against the following devices:

3D Accu-I-tomo XYZ Slice View Tomograph MCT-1EXF (K052587)

6. Description of the device:

The MCT-1EX-1F8/F17 is an x-ray imaging device that acquires 360 degree rotational sequence of the head and neck areas, mainly for dentistry. The imaging data are once stored at three dimensional matrix of the examined volume, and are reconstructed by image processing through the Personal Computer, then finally displayed as both two and three dimensional images on the monitor.

It consists of rotation arm part, main body part, base part and accessories including personal computer and software.

This MCT-1EX-1F8/F17 is a slightly modified device from the MCT-1EXF (K#052587) of J.MORITA MFG. CORP replacing the solid state x-ray imaging device of "Flat Panel Detector (FPD)" with some other additional modifications.

As the main hardware and software are used common, this new MCT-1EX-1F8/F17reserves the same general intended use, similar principles of operation, and similar technological characteristics as the predicate device MCT-1EXF. It is self-explanatory that the MCT-1EX-1F8/F17 is substantially equivalent to MCT-1EXF.

7. Intended Use

Intended use

MCT-1EX-1F8/F17 is intended to be used for head and neck three dimensional X-ray Computed Tomography by a limited, cone-shaped x-ray beam projected onto a flat panel X-ray detector, to be operated and used by doctors, dentists, properly licensed professionals and other legally qualified professionals.

Applications include diagnosis for Temporal, Nasal, Orbita, Maxilla, Mandibula, Cerviales, Cranium and Basicranium area.

8. Safety and effectiveness of the device

SUBSTANTIAL EQUIVALENCE

The MCT-1EX-1F8/F17 covered by this submission is developed from our legally marketed device, MCT-1EXF (K#052587), modified slightly by replacing FPD to enlarge the radiographic area by using larger field of FPD, without any significant changes for the other components or performances. The comparison including the differences are described at the Table-1 titled " Comparison chart: MCT-1EX-1F8/F17 to MCT-1EXF" at Attachment 5 of this submission.

As is shown in the following comparison summary chart and table , MCT-1EX-1F8/F17 is substantially equivalent to MCT-1EXF because they have similar general intended uses, technological characteristics and operating principles. As described above, any differences in the technological characteristics do not raise any new issues of safety or effectiveness.

Table-1 Comparison summary chart

	This new submission	Predicate device	Difference
Name of model	MCT-1EX-1F8/F17	MCT-1EXF	Different
Manufacturer	J.MORITA MFG. CORP.	J.MORITA MFG. CORP.	Identical
Construction	1)Slightly modified Rotating arm 2) The same conventional base/chair/support tower	1)Conventional Rotating arm 2)Conventional base/chair/support tower	Similar
Image Receptor	Flat panel detecter	Flat panel detecter	Same
Performance spec.	International standards	International standards	Similar
Mechanical	Morita made mechanism	Morita made mechanism	Similar
Electrical	Morita made electric circuit	Morita made electric circuit	Similar
Software	Morita made software	Morita made software	Slightly Different
Testing	Mainly done by VDE	Mainly done by VDE	Same

Table-2 Comparison summary table

FDA file reference number

Attachment inside notification submission file 510k FDA website print out.

TECHNOLOGICAL CHARACTERISTICS	Comparison result	
Model name of Predicate Device	MCT-1EXF	
510(k) number of Predicate Device	K052587	
Indication for use	Identical	
Target population	Similar	
Design	Slightly changed	Note-1
Materials	Slightly changed	Note-2
Performance	Slightly changed	Note-3
Sterility	Similar	
Biocompatibility	Similar	
Mechanical safety	Similar	
Chemical safety	Similar	
Anatomical sites	Similar	
Human factors	Similar	
Energy used and/or delivered	Similar	
Compatibility with environment and other devices	Similar	
Where used	Identical	
Standards met	Identical	
Electrical safety	Identical	
Thermal safety	Identical	
Radiation safety	Identical	

Note-1

This new devices are designed to enlarge the sizes of radiographic areas, so that some modifications are done over the arm assembly, FPD and software or else

Note-2

The new larger size FPD is introduced.

Note-3

The enlarged sizes of radiographic areas are obtained with higher image quality such as high speed, high fidelity or high resolution other than standard mode.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAY 20 2010

J. Morita USA, Inc.
% Mr. Keith A. Barritt, Attorney
Fish & Richardson P.C.
1425 K St. N.W., Suite 1100
WASHINGTON DC 20005

Re: K073695
Trade/Device Name: 3D Accu-I-tomo Slice View Tomograph, Model MCT-1EX-1F8/F17
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 24, 2008
Received: March 25, 2008

Dear Mr. Barritt:

This letter corrects our substantially equivalent letter of April 9, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number : unknown

Device Name: 3D Accu-I-tomo XYZ Slice view tomograph, Model: MCT-1EX-1F8/F17

Indications for Use:

The Model MCT-1EX-1F8/F17 is a x-ray imaging device that acquires a 360 degree rotational sequence of the head and neck areas, including the ENT and dento-maxillofacial areas, for use in diagnostic support. The device accomplishes this task by reconstructing a three dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images.

The device is operated and used by physicians, dentists and x-ray technologists.

Prescription Use (Part21CFR801 Subpart D) AND/OR Over-The-Counter Use (Part21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(K) Number : _____

Prescription Use ✓ (Part21CFR801.109) or Over-The-Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073695